UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 07-APR-2000

SUBJECT: PP# 8F04941. Prohexadione-Calcium, in/on Peanuts, Pome Fruits, and Cattle Meat Byproducts (Kidney). **Review of Amendments Dated 2/18/00 & 3/16/00 Submitted in Response to HED's Memo of 11/22/99.** Revised Sections B & F and Storage Stability Data. MRID# 45067901. Barcodes D264488 & D264533. Chemical 112600. Case 289440. Submission#s S577553 & S577609.

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K-I Chemical U.S.A. has submitted a petition for the establishment of permanent tolerances for residues of a new plant growth regulator, prohexadione-calcium (calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate), in/on peanuts, pome fruits, and cattle meat byproducts (kidney). Concurrently, the petitioner is requesting Section 3 registration for end-use products containing prohexadione-calcium as the active ingredient; a 27.5% dry flowable (DF) formulation (Product Name = Apogee™, EPA File Symbol No. 63588-RR); and a 75% DF formulation (Product Name = Baseline™, EPA File Symbol No. 63588-O). Apogee™ is intended for use on apple and pear trees and Baseline™ is intended for use on peanuts. Section F of the petition proposes the establishment of tolerances for residues of prohexadione-calcium *per se* [calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate] in/on the following raw agricultural commodities (RACs):

Peanut	1.0 ppm
Peanut, hay	0.6 ppm
Fruit, pome, group	3.0 ppm

Cattle, goats, hogs, horses, and sheep, kidney . 0.1 ppm
Cattle, goats, hogs, horses, and sheep, meat byproducts, except kidney . . . . . 0.05 ppm

The current amendment addresses deficiencies identified in HED's previous review (Memo, G. Kramer 11/22/99; D252547).

Executive Summary of Chemistry Deficiencies

- Agency validation of analytical enforcement method for plants.
- Need storage stability data on the processed commodities of peanuts.

CONCLUSIONS/RECOMMENDATIONS

Provided that Agency validation of analytical enforcement method for plants is successful, HED concludes there are no residue chemistry data requirements that would preclude the establishment of permanent tolerances for residues of prohexadione-calcium in/on pome fruit, peanut and animal RACs. Registration of Apogee™ and Baseline™ should be made conditional upon the submission of additional storage stability data as specified below. A human-health risk assessment will be prepared as a separate document.

DETAILED CONSIDERATIONS

Deficiency - Conclusion 2 (from Memo, G. Kramer 11/22/99; D252547)

2. The proposed uses of prohexadione-calcium on apples and pear (the representative commodities of pome fruits) were adequately described on the Apogee™ label. **However, a revised Baseline™ label, which includes a 30-day plantback restriction for all rotational crops (except peanuts), should be submitted.**

Petitioner's Response: Submission of a Baseline™ label, which includes a 30-day plantback restriction for all rotational crops (except peanuts).

HED's Conclusion: The requested information has been provided. This deficiency is now resolved.

Deficiency - Conclusions 14, 15a & 18a (from Memo, G. Kramer 11/22/99; D252547)

14. ...However, the correct commodity definitions are "Peanut" and "Peanut, hay." The Agency has also determined that "calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate" is the preferred chemical name for prohexadione-calcium (Memo 5/18/99, H. Podall; D253852). **A revised Section F is required.**

15a. ...However, the correct commodity definition is "Fruit, pome, group." **A revised Section F is required.**

18a. ...By extrapolation of the average residues at ~2x, ~7x, and ~24x the anticipated maximum dietary burden for beef cattle, HED concludes that the appropriate tolerance levels are 0.1 ppm for residues of prohexadione-calcium in cattle kidney and 0.05 ppm for meat byproducts (except kidney). **The petitioner is required to submit a revised Section F to amend the proposed tolerance from "cattle, meat byproduct (kidney)" to "cattle, goats, hogs, horses, and sheep, kidney" and to add "cattle, goats, hogs, horses, and sheep, meat byproducts, except kidney."**

Petitioner's Response: The revised Section F of the petition proposes the establishment of tolerances for residues of prohexadione-calcium [calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate] in/on the following commodities:

Peanut	1.0 ppm
Peanut, hay	0.6 ppm
Fruit, pome, group	3.0 ppm
Cattle, goats, hogs, horses, and sheep, kidney	0.1 ppm
Cattle, goats, hogs, horses, and sheep, meat byproducts, except kidney	0.05 ppm

HED's Conclusion: The requested information has been provided. This deficiency is now resolved.

Deficiency - Conclusions 12c & 12d (from Memo, G. Kramer 11/22/99; D252547)

12c. According to the petitioner, no storage stability data were submitted for pome fruits because initial analyses of field samples were completed within one month. HED, however, notes that some residues reported in the pome field trials include values for samples which were re-analyzed after 3 months of storage. Given the observed instability of prohexadione-calcium residues in/on peanut nutmeat, the petitioner is required to provide confirmatory storage stability data on pome fruits reflecting an interval of three months. The petitioner has indicated that a freezer storage stability study for prohexadione-calcium and the metabolite BX-112-I5 in apples has been initiated and is scheduled to be completed by November 2000.

12d. No storage stability data are required for the processed commodities of apples because analyses of samples were completed within one month of sampling. However, storage stability data on the processed commodities of peanuts, reflecting an interval of 7 months, are required.

Petitioner's Response: Submission of:

45067901 Stewart, J (2000) Storage Stability of BAS 125W and

Metabolite BW 125 21F in Apples. Interim Report: Lab Project Number: 98122.

Both prohexadione-calcium and the metabolite BX-112-I5 are stable during storage in apples for at least 13 months.

HED's Conclusion: The requested information has been provided for apples. However, storage stability data on the processed commodities of peanuts, reflecting an interval of 7 months, are still required. This deficiency is partially resolved.

cc: PP#8F04941, G. Kramer (RAB1)
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